residue on ignition, specific rotation, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 12 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution of convenient concentration. Dilute an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of netilmicin per milliliter (estimated).

(2) *Loss on drying.* Proceed as directed in § 436.200(c) of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 40 milligrams per milliliter.

(4) *Residue on ignition*. Proceed as directed in § 436.207(a) of this chapter.

(5) *Specific rotation*. Use an aqueous solution containing 3 milligrams of sample per milliliter. Proceed as directed in § 436.210 of this chapter, using a 1.0–decimeter tube, and calculate the specific rotation on an anhydrous basis.

(6) *Identity*. Proceed as directed in § 436.318 of this chapter, except:

(i) Prepare sample and standard solutions containing 10 milligrams of netilmicin per milliliter;

(ii) Use 5 microliters of the solutions to spot the chromatography plate;

(iii) Remove the plate from the tank after 1.5 hours; and

(iv) Netilmicin sulfate appears as a brown spot.

[48 FR 18800, Apr. 26, 1983; 48 FR 22144, May 17, 1983, as amended at 55 FR 11584, Mar. 29, 1990]

§ 444.50 Paromomycin sulfate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Paromomycin sulfate is the sulfate salt of a kind of paromomycin or a mixture of two or more such salts. It is a creamy-white to light-yellow powder. It is so purified and dried that:

(i) Its potency is not less than 675 micrograms per milligram on an anhydrous basis.

(ii) [Reserved]

(iii) Its loss on drying is not more than 5.0 percent.

(iv) The pH of a 3.0 percent aqueous solution is not less than 5.0 and not more than 7.5.

(v) Its specific rotation at 25° C. in water is not less than +50° and not more than +55° on an anhydrous basis.

(vi) Its residue on ignition is not more than 2.0 percent.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5(b) of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, loss on drying, pH, specific rotation, and residue on ignition.

(ii) Samples of the batch: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Further dilute the stock solution with solution 3 to the reference concentration of 1.0 microgram of paromomycin per milliliter (estimated).

(2) [Reserved]

(3) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using a 3.0 percent aqueous solution.

(5) *Specific rotation*. Accurately weigh approximately 1.25 grams of the sample into a 25-milliliter volumetric flask. Dissolve in a few milliliters of water, add water to volume, and mix. Proceed as directed in § 436.210 of this chapter, using a 2.0-decimeter polarimeter tube. Calculate the specific rotation on an anhydrous basis.

(6) *Residue on ignition*. Proceed as directed in § 436.207(a) of this chapter.

[39 FR 19046, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]